K010847

JUN 1 9 2001

510 (k) Summary

Summary of 510 (k) safety and effectiveness information upon which the substantial equivalence determination is based:

Prepared: June 12, 2001

Applicant: Avanta Orthopaedics, Inc.
9369 Carroll Park Drive, Suite A
San Diego, CA 92121

Telephone: 858-452-8580
Fax: 858-452-9945
Contact: Louise M. Focht

Device Name:	Pin cap
Device Trade Name:	K'fix
Device Classification:	II
Reviewing Panel:	87
Regulation Number	888.3040
Product Code:	NDL
Predicate Device:	Jurgan Pin Ball (K831072)
Registration Number:	2030506
Owner Operator Number:	9001389

Device Description:

The K'fix is an external disposable device, designed to fit all protruding pins from 0.7 to 2mm diameter. The device is intended to provide protection from hazards of protruding pins and wires. The device are made of plastic materials which screw onto the pin. When the device is tightened to the pin the exposed wire is protected against snagging, and stubbing.

Indications for Use:

The K'fix is intended for protection of the protruding pin commonly used in traumatologie. Recommended for children and adults.

Comparison to Predicate Device:

The legally marketed predicate device to which this device is substantially equivalent is Jurgan Pin Ball.

Regulatory Class: II
Product Code: NDL

Item	*K'fix*	*Jurgan Pin Ball*
Product Name	K'fix	Jurgan Pin Ball
Use	Single use	Single use
Fixation	Screw	Screw
Constraint	Not applicable	Not applicable
Material	Polyacetal	Plastic
Sizes	0.7 through 2 mm	.7mm through 6mm

Similarities of the K'fix and Jurgan Pin Ball include;

Both devices are intended for single use only;

Both devices are intended for external use;

Both devices are used to protect protruding pins from snags and stubbing;

Both devices are made of industry standard materials. No new materials are introduced in either product;

Both devices are comparably sized;

Both devices have similar indications for use.

Summary:

The device and the predicate device have similar design characteristics and intended use. The new device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Louise M. Focht
Avanta Orthopaedics, Inc.
9369A Carroll Park Drive
San Diego, California 92121

Re: K010847
Trade Name: K'fix pin cap
Regulation Number: 888.3040
Regulatory Class: II
Product Code: NDL
Dated: March 19, 2001
Received: March 21, 2001

Dear Ms. Focht:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (If Known): K010847
Device Name: K'fix

Indications for Use:

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Prescription Use (Yes)/No Or Over the counter use Yes/No

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010847